



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

g1792d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER

NWE-39-01W

VIA FEDERAL EXPRESS

September 26, 2001

Stephen Birge
President and Co-Owner
Black River Produce Earth Brothers Ltd.
d.b.a. Black River Produce
Route 103
Proctorsville, VT 05153

Dear Mr. Birge:

We inspected your firm, located on Route 103, Proctorsville, VT, on August 13 through 15, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, which were previously brought to your attention during previous inspections, cause your seafood products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, on several occasions, your firm did not record any temperatures/observations at the receiving critical control point, (CCP) to control the histamine hazard listed in your HACCP plan for scombroid species. Also, your firm is not targeting histamine producing fish for temperatures at this receipt stage. For example, your firm may receive numerous species of fish, and the temperature that is taken at this step may not be of histamine producing fish.

Also, there were no records to demonstrate that the storage temperature is being recorded as required by your HACCP plan, i.e. there were no temperature records available from February 13, 2001 to the present.

- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for histamine producing fish does not list a critical limit at the storage critical control point to control the histamine hazard.
- You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for histamine producing fish lists a monitoring procedure at the receipt step that is not adequate to control the histamine hazard. For example, your plan should either have records demonstrating the fish was held at [REDACTED] or lower throughout its transport OR assure that there is an adequate quantity of ice surrounding the product upon delivery. Currently, your temperature records for this receipt step do not demonstrate the product is held at [REDACTED] or lower during its transport.


We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your modified HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



GARY COSTELLO
District Director
New England District Office

Cc:

Mark Curran
Secretary, Treasurer and Co-Owner
Black River Produce Earth Brothers Ltd.
d.b.a. Black River Produce
Route 103
Proctorsville, VT 05153